

REMARKS

Claims 1-6 and 24-35 are pending in the present application. Claims 1-6 are amended herein. New claims 24-35 have been added. Favorable consideration of the pending claims is respectfully requested.

Applicants' Response to 35 U.S.C. §112, Second Paragraph Rejection

Claims 2 and 4-6 are rejected under 35 U.S.C. §112, second paragraph, as allegedly being indefinite. Applicants have amended claims 2, 4 and 6 to address the matters raised by the Examiner. In particular, amended claims 2 and 4 each recite a single additional method step. Amended claim 6 recites a set of conditions for performing the method.

Further, with regard to claim 4, Applicants submit that it does not contradict the parent claim 3. The progress of dissolving is not necessarily monitored by repeated measurements in one sample. Rather, different samples in the array have different time points in the dissolution assay, thereby providing data as a function of time. See, e.g., Examples 3 and 4 in the present application.

In view thereof, Applicants respectfully request reconsideration and withdrawal of the Section 112, second paragraph rejection.

Applicants' Response to 35 U.S.C. §102(e) Rejection over Cima

Claims 1-6 are rejected under 35 U.S.C. §102(e) as allegedly being anticipated by U.S. Patent Publication No. 2002/0048610 A1 to Cima et al. (hereinafter "Cima"). Applicants respectfully request reconsideration on the basis that Cima fails to disclose each and every element of Applicants' claims, as amended herein.

The Examiner asserts that Cima teaches a method for determining how the solubility, dissolution or stability of polymorphs depend on the solid form by preparing an array of samples with a controlled amount of the compounds-of-interest, forming a liquid portion by adding a solvent and determining how much compound-of-interest is dissolved in the liquid portion depending on its form. The Examiner concludes that Cima's disclosure covers the subject matter of Applicants' claims.

Applicants have amended independent claims 1, 3 and 5 to further define the invention. The amendments clarify that Applicants' methods are directed to determining how the solubility, dissolution or stability is affected by the physical or chemical form of the solid compound-of-interest itself. In particular, the amended claims recite the step of "preparing an array of samples, each comprising a controlled amount of the compound-of-interest,

wherein the physical or chemical form of the compound-of-interest in at least two of the samples is different.”

In Applicants’ present claims, the initial samples in the array are prepared with different physical or chemical forms of the solid compound-of-interest itself. The different physical or chemical forms of a compound are described on page 5, paragraph [0031] of the present application:

As used herein and unless otherwise indicated, the term “form” encompasses the physical and chemical forms of a compound. Examples of physical forms include, but are not limited to, solid, liquid (e.g., oil), and gas. The physical form of a solid encompasses, but is not limited to, particle size (e.g., the average particle size or mean distribution of particle sizes of a powder), whether or not a compound is crystalline or amorphous or the degree to which it may be one or the other, the crystal form of a crystalline compound (i.e., its crystal structure), crystal habit, and color. Chemical forms of a compound include, but are not limited to, salts, free-bases, solvates (e.g., hydrate), co-crystals, and clathrates.

Addition of a solvent, in Applicants’ claims 1 and 3, allows for a determination as to how these different physical or chemical forms of the solid compound-of-interest affect the compound’s solubility and dissolution properties. Exposure of the samples to a condition that may affect stability, in Applicants’ claim 5, allows for a determination as to how the different physical or chemical forms of the solid compound-of-interest affect the compound’s property of stability. Cima fails to disclose or suggest such methods.

More specifically, nowhere in Cima is it taught to initially prepare an array of samples wherein the physical or chemical form of the solid compound-of-interest in at least two samples is different, and then forming a liquid portion of each sample by adding a solvent and determining how much compound-of-interest dissolved in the liquid portion (claim 1), as a function of time (claim 3), or how exposure to a condition affected stability of the compound-of-interest (claim 5).

Moreover, dependent claim 2, 4 and 6, as well as new dependent claims 24-35 add additional steps to the methods and conditions for performing the methods that are not disclosed or suggested in Cima.

In view of the foregoing amendments and remarks, Applicants respectfully submit that claims 1, 3, and 5, and thus claims 2, 4, 6 and 24-35 which depend therefrom, are patentable over Cima. Reconsideration and withdrawal of the Section 102 rejection is respectfully requested.

CONCLUSION

The Commissioner is hereby authorized to charge any deficiency or credit any overpayments necessitated by this Amendment to Deposit Account No. 10-0750/TPI5020USPCT1.

Early favorable action on the merits is respectfully requested.

Respectfully submitted,

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